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EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/529,157	TROTTER ET AL.	
	Examiner	Art Unit	
	RONALD T. NIEBAUER	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 March 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16,18,19,22 and 23* is/are pending in the application.

4a) Of the above claim(s) *7-10 and 12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,11,13-16,18-19,22-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants amendments and arguments filed 3/11/08 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed is herein withdrawn.

Claims 1,3-4,6,11,13-16,18-19,22 have been amended. Claim 23 has been added as a new claim. Claims 17,20-21 have been cancelled.

Claims 7-10,12 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention/species, there being no allowable generic or linking claim.

Claims 1-6,11,13-16,18-19,22-23 are under consideration.

The elected species of peptide (SEQ ID NO:19 (Gly-Arg-Gly-Asp)) and agent (antimicrobial agent) were found in the prior art as cited below.

Claim Objections

The following objections are necessitated due to applicants amendments.

Claim 11 is objected to for not ending in a period. MPEP § 804.01(m) states that, "Each claim begins with a capital letter and ends with a period. Periods may not be used elsewhere in the claims except for abbreviations. See *Fressola v. Manbeck*, 36 USPQ2d 1211 (D.D.C. 1995)."

Appropriate correction is required.

Applicant is advised that should claim 1 be found allowable, claim 23 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application

are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

It is noted that claim 1a recites a donor layer and claim 23a recites an absorbent layer. However, the difference in wording does not distinguish the claims from one another. The specification (page 11) recites donor layer and absorbent layer however no specific definitions are provided to distinguish the terms.

Claim Rejections - 35 USC § 112

The following rejections are necessitated due to applicants amendments.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6,15-16,18,22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 recites that the sequences consist of 3 to 15 amino acids. However, claim 1 recites that the matrix comprises cross-linkages which comprise oligopeptide sequences. It is noted that the phrase 'consisting of' is closed language (see MPEP section 2111.03). If the oligopeptides consisted of 3 to 15 amino acids there would be no cross-linkages since cross-linkages are not a part of the amino acids. As such, the oligopeptides include other elements in addition to the amino acids.

Claims 15-16 recite 'the wound contacting layer'. There is insufficient antecedent basis for this limitation in the claims. Claim 1 recites a 'donor layer' and a 'barrier layer', however claim 1 does not recite a 'wound contacting layer'. It is noted that claim 15 recites 'may comprise'. The phrase "'may comprise' renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d). Further, claim 16 recites that the 'intermediate layer' comprises the matrix. However, claim 1 recites that the 'barrier layer' comprises the matrix. As such, it is unclear how many layers are present. It is unclear how the 'intermediate layer' and the 'barrier layer' both comprise the matrix. Claim 16 recites that there is an 'outer layer'. However, the claim also recites that there is a 'wound contacting layer'. Based on the name, one would expect the 'wound contacting layer' to be the outer layer. As such, the additional 'outer layer' renders the claims unclear. As such the configuration and layers of claims 15-16 are unclear.

Claim 18 recites the phrases 'apertured sheet' and 'applied thereto in occlusive fashion'. The claim is unclear. In particular, the phrase 'occlusive fashion' is unclear. Although the terms are discussed in the specification (page 12), specific definitions are not provided. It is not clear what falls within the meets and bounds of the claim.

Claim 22 recites that the wound dressing comprises an absorbent layer and/or a backing layer. However, it is unclear if the recited layers are in addition to the layers recited in claim 1 or if the layers are specific types of donor layers, for example. It is noted that claims 1 and 23 are similar in scope and that claim 1a recites a donor layer and claim 23a recites an absorbent layer. However, the difference does not distinguish the claims from one another. The specification (page 11) recites donor layer and absorbent layer however no specific definitions are provided to distinguish the terms.

Claim Rejections - 35 USC § 112

Previously claims 1-3 were rejected as failing to comply with the written description requirement. Claims 1-3 remain rejected as failing to comply with the written description requirement. Since the claims have been amended and new claims have been added the rejection adapted to the instant claims is below.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6,13-16,18-19,22-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

> "To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); In re Gostelli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966." Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.* the court stated:

> "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *Fiers*, 984 F.2d at 1171, 25 USPQ2d 1601; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus …") *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP § 2163. The MPEP does state that for a generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP § 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP § 2163. Although the MPEP does not define what constitute a sufficient number of representative species, the courts have indicated what do not constitute a representative number of species to adequately describe a broad generic. In *Gostelli*, the courts determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872, F.2d at 1012, 10 USPQ2d at 1618.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP § 2163. While all of the factors have been considered, a sufficient amount for a *prima facie* case are discussed below.

In the instant case, the claims are drawn to wound dressing compositions comprising a matrix comprising oligopeptide sequences which are cleavable by a protease associated with wound fluid.

(1) Level of skill and knowledge in the art:

The level of skill in the art is high.

(2) Partial structure:

The oligopeptide sequences are described as being cleavable by a protease. The claims (such as claim 11) give examples of several oligopeptide sequences. However, nearly every protein is cleavable by a protease. For example, Matthews (Biochemistry 1996 as cited previously) teach numerous proteases such as trypsin, pepsin thrombin, and papain that would cleave an oligopeptide sequence. For example trypsin cleaves when R1 is Lys or Arg (see Table 5.4 of Matthews). If one considered a 10 amino acid peptide (R1-R10) oligomer with either Lys or Arg at R1 and any other amino acid except proline at R2 and any amino acid at the other positions there would be at least 20^8 (over 2 billion) possible peptides. Even though approximately 30 different oligopeptide sequences are recited in the specification, the recited peptides do not represent the genus. One of skill in the art would not recognize that the applicant was in possession of wound dressings with oligopeptide sequences of the scope of the genus of claims 1 and 23 for example.

The dressing is described as a matrix comprising polymers and a therapeutic agent. The specification (page 5) provides examples of numerous polymers. Claim 5 is drawn to a specific polymer. Claim 3 is drawn to polymers that are not degraded by protease or other factors. However, no examples are provided of a matrix comprising polymers and a therapeutic agent. An example appears on page 9 lines 19-25 which recite specific oligopeptide sequences and a

specific polymer. This example does not represent the claimed invention because the example does not recite a therapeutic agent. Therapeutic agents are a component of the wound dressing. The agents can be a variety of things (claim 13, page 10). However, no specific examples of wound dressings are provided. Although examples have been provided of components of the wound dressing no examples have been provided of a wound dressing as claimed. The example on page 9 lines 19-25 does not recite any agent.

There is substantial variability in the genus. Since there are a substantial variety of polypeptides possible within the genus, the examples do not constitute a representative number of species and do not sufficiently describe the genus claimed (see Gostelli above).

(3) Physical and/or chemical properties and (4) Functional characteristics:

The oligopeptide sequences are described as being cleavable by a protease. Claims 1,23 recite that the protease is associated with wound healing. In particular the protease is described as being associated with would fluid, (claim 1,23 for example) wound infection or ulcer formation (claim 2). Claims 1,23 recite that the wound dressing is such that the rate of release of the therapeutic agent increases in the presence of the protease. However, there is no correlation provided between structure and function. No common structural attributes identify the members of the genus, in particular the oligopeptide sequences. For example, the recitation of 'associated with wound healing' does not lead one to particular wound dressing compositions or specific oligopeptide sequences. From the phrase 'rate of release of the therapeutic agent increases in the presence of the protease', one of skill in the art would not conclude any structural information. No common core sequence is taught for all the possible alternatives. One of skill in the art would

reasonably conclude that the disclosure fails to provide a representative number of species or sufficient relevant identifying characteristics.

Regarding the polymer it is noted that claim 3 is drawn to polymers that are not degraded by protease or other factors. However, there is no correlation provided between structure and function. No common structural attributes identify the members of the genus, in particular the polymers that are not degraded by protease or other factors. From the phrase 'are not degraded by the protease or other factors', one of skill in the art would not conclude any structural information. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species or sufficient relevant identifying characteristics.

(5) Method of making the claimed invention:

The specification does not describe any specific embodiments of wound dressings nor methods of making them.

As stated *supra*, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable that claim(s) 1,23 are broad and generic, with respect to all possible wound dressings encompassed by the claims. The possible structural variations are limitless to any agent, polymer, and peptide meeting the claim limitations. Although the claims may recite some functional characteristics, the claims lack written description because there is no disclosure of a correlation between function and structure of the components beyond those components specifically disclosed in the examples in the specification. Moreover, the specification lacks sufficient variety of species to reflect this variance in the genus. While having written description of polypeptides identified in the

specification tables and/or examples, the specification does not provide sufficient descriptive support for the myriad of wound dressings embraced by the claims.

The description requirement of the patent statue requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

Response to Arguments Written Description

Applicants argue that claim 1 is not directed to all proteases but rather is directed to a particular genus of proteases. Applicants argue that approximately 30 different oligopeptide sequences are recited in the specification. Applicants argue that it has not been shown that particular cited proteases are associated with wound fluid. Applicants argue that the specification contains a sufficient written description of the invention.

Applicant's arguments filed 3/11/08 have been fully considered but they are not persuasive.

Although applicant argues that the claims are drawn to a particular genus of proteases, there is no correlation provided between structure and function such that one could identify the common structural attributes of the oligopeptide sequences. For example, the recitation of 'associated with wound healing' does not lead one to particular wound dressing compositions or

specific oligopeptide sequences. From the phrase 'rate of release of the therapeutic agent increases in the presence of the protease', one of skill in the art would not conclude any structural information. As such one would not recognize which proteases are associated with wound fluid. It is noted that the claim (claim 11) that is drawn to specific sequences has not been included in this written description rejection. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species or sufficient relevant identifying characteristics.

Claim Rejections - 35 USC § 102

Previously claims 1-3 were rejected as being anticipated by Sojomihardjo et al. (WO 96/40829). Claims 1-3 remain rejected as being anticipated by Sojomihardjo et al. (WO 96/40829). Since the claims have been amended and new claims have been added the rejection adapted to the instant claims is below.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4,6,11,13-16,18-19,22-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Sojomihardjo et al. (WO 96/40829 as cited previously).

Sojomihardjo teach (claim 18 page 53) an article comprising a crosslinked polypeptide (i.e. a matrix comprising polymers – polypeptides are polymers) having a biologically active material (i.e. therapeutic agent) entrapped therein. Sojomihardjo teach the compositions as wound dressings (abstract last sentence, claim 6). Sojomihardjo teach the crosslinked polypeptide as microcapsules containing a drug for drug delivery (page 20 lines 10-13). Sojomihardjo teach that the crosslinked microcapsules will allow for release of the entrapped drug and that over time there should be a sustained release profile for the drug (page 20 lines 17-22).

Since Sojomihardjo teach encapsulation there are different layers including an inner layer with the biologically active material as recited in claim 1a, 23a and an outer layer with the crosslinked polymer as recited in claim 1b,23b of the instant invention. It is noted that claim 1,23 recites 'that the rate of release of the therapeutic agent increases'. Since the art meets the structural limitations of the claim, it must necessarily meet the functional limitations (MPEP section 2112.01 II).

Since Sojomihardjo teach entrapment and encapsulation (claim 18 page 53, page 20 lines 10-13) the limitations recited in claims 14,19 of the instant invention are met

It is noted that although unclear (see 112 2nd) the configurations and layers of claims 15-16,18,22 have been given the broadest reasonable interpretation (see MPEP section 2111) such that Sojomihardjo meet the claim limitations. In particular the entrapment and encapsulation (claim 18 page 53, page 20 lines 10-13) creates the layers as recited in the instant claims. The term 'occlusive fashion' of claim 18 has been interpreted to mean enclosed and thus encapsulation meets the claim limitations.

Sojomihardjo teach synthetic peptides (peptides are polymers) (page 8 line 21, page 10 line 4, claim 2) thus meeting the limitation recited in claim 4 of the instant invention.

Sojomihardjo teach GRGD (which is identical to the elected peptide sequence) (page 15 line 26) as a crosslinkable peptide thus meeting the limitations of claims 6,11 of the instant invention. Although unclear claim 6 has been given the broadest reasonable interpretation (see MPEP 2111) such that the oligopeptide sequences are open to crosslinking and do not merely consist of amino acid sequences. It is noted that although thrombin is recited in claim 11 it is not a necessary component as claimed. It is noted that the peptide of Sojomihardjo meet the structural limitations of the claims thus the functional limitations of claims 2-3 for example are necessarily met absence evidence to the contrary. Further, since thrombin is described as being involved in infection (specification page 8 lines 1-6) and as claimed (claim 11) the oligopeptide sequence GRGD is cleavable by thrombin the limitations of claim 2 are met.

Sojomihardjo teach the active material as an antibiotic (which is the elected agent species) (page 20 line 29-31, more generally on page 17 line 25) in the matrix of cross-linked protein (page 20 line 23-25) thus meeting the limitations of claim 13 of the instant invention.

Response to Arguments 102

Applicants argue that claim 1 has been amended. Applicants argue that Sojomihardjo teach that the polypeptides can entrap biologically active material and impart physiological activity. Applicants argue that in contrast to Sojomihardjo the instant invention teach layers. Applicants argue that Sojomihardjo does not teach a donor layer.

Applicant's arguments filed 3/11/08 have been fully considered but they are not persuasive.

It is noted that section 2111 of the MPEP states that claims are to be given the broadest reasonable interpretation. In the instant case Sojomihardjo does not use the word layers. However, no specific definition of layer is provided in the instant specification. As such the term layer is given the broadest reasonable interpretation. One does not read into the claims that the 'layers' as claimed by applicant excludes the prior art.

Sojomihardjo teach the crosslinked polypeptide as microcapsules containing a drug for drug delivery (page 20 lines 10-13). Sojomihardjo teach that the crosslinked microcapsules will allow for release of the entrapped drug and that over time there should be a sustained release profile for the drug (page 20 lines 17-22). Since Sojomihardjo teach encapsulation there are different layers including an inner layer with the biologically active material as recited in claim 1a, 23a and an outer layer with the crosslinked polymer as recited in claim 1b,23b of the instant invention. As such Sojomihardjo meet the claimed limitations.

Claim Rejections - 35 USC § 103

The following rejections are necessitated due to applicants amendments.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6,11,13-16,18-19,22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sojomihardjo et al. (WO 96/40829 as cited previously) and Ulbrich et al. (Biomaterials 1980 v1 199-204 as cited in IDS).

As discussed above Sojomihardjo et al. disclose the elements of claims 1-4,6,11,13-16,18-19,22-23 of the instant invention.

Sojomihardjo does not expressly teach the polymer N-(2-hydroxypropyl) methacrylamide (HPMA) as recited in claim 5.

Sojomihardjo teach (page 29 lines 13-34) the use of the proteins crosslinked in the presence of other monomers to form copolymers. In particular Sojomihardjo teach (page 29 line 18) the use of methacrylamide as a copolymer. Sojomihardjo teach that the use of copolymers is advantageous because the diverse, unique, and advantageous properties of the component materials can be combined (page 29 lines 31-34).

Ulbrich teach copolymers of N-(2-hydroxypropyl) methacrylamide (HPMA) joined by crosslinks containing oligopeptide sequences (abstract). Ulbrich describe applications as biodegradable polymers. Since Sojomihardjo also teach similar applications such as crosslinked microcapsules which allow for release of the entrapped drug and that over time there should be a

sustained release profile for the drug (page 20 lines 17-22). Since Sojomihardjo teach that the use of copolymers is advantageous because the diverse, unique, and advantageous properties of the component materials can be combined (page 29 lines 31-34) one would be motivated to use various copolymers. Since Sojomihardjo teach (page 29 line 18) the use of methacrylamide as a copolymer one would be motivated to use a specific methacrylamide, N-(2-hydroxypropyl) methacrylamide (HPMA), which has been described by Ulbrich. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

Taken together the copolymer (N-(2-hydroxypropyl) methacrylamide (HPMA) as described by Ulbrich with the GRGD peptide sequence (page 15 line 26) as taught by Sojomihardjo) meet the claimed limitations.

It has been recently held that "Neither §103's enactment nor *Graham*'s analysis disturbed the Court's earlier instructions concerning the need for caution in granting a patent based on the combination of elements found in the prior art." KSR v. Teleflex, 550 U.S. ___, 82 USPQ2d 1385, 1389 (2007). The KSR court stated that "a combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." KSR at 1389.

Furthermore, The KSR court concluded that "obvious to try" may be an appropriate test under 103. The Supreme Court stated in *KSR*

> When there is motivation
>
> > "to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103." *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, ___, 82 USPQ2d 1385, 1397 (2007).

In the instant case the claims would have been obvious because the substitution of one known element (N-(2-hydroxypropyl) methacrylamide (HPMA) as taught by Ulbrich) for another (methacrylamide as taught by Sojomihardjo) would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Double Patenting

Previously claims 1-3 were rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over specific copending applications. Claims 1-3 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over specific copending applications. Since the claims have been amended and new claims have been added the rejection adapted to the instant claims is below.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting

ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-6,13-16,18-19,22-23 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 7,361,634 ('634) (previously identified as copending Application No. 10/554,375). Although the conflicting claims are not identical, they are not patentably distinct from each other.

'634 teach a wound dressing comprising a therapeutic agent and a matrix comprising HPMA and specific oligopeptide sequences (claims 1-10) which reads on claims 1-6,13-16,18-19,22-23 of the current invention. In particular HPMA (claim 1) meets the limitations recited in claims 4-5 of the instant invention. The oligopeptide (claim 1) meets the limitations recited in claim 6 of the instant invention. '634 teach therapeutic agents (claim 1) as in claim 13 of the instant invention. It is noted that although unclear (see 112 2nd) the configurations and layers of the instant claims have been given the broadest reasonable interpretation (see MPEP section 2111) such that '634 (for example see claims 3-10) meet the claim limitations. It is noted that the peptides of '634 meet the structural limitations of the claims thus the functional limitations of claims 2-3 for example are necessarily met absence evidence to the contrary.

Claims 1-3,13,23 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 (3/24/05 claim set) of copending

Application No. 10/529,156 ('156). Although the conflicting claims are not identical, they are not patentably distinct from each other.

'156 teach a wound dressing comprising a therapeutic agent (see claim 6) and a layer comprising oligopeptide sequences (claim 1,3 for example) which reads on claims 1-3,13,23 of the current invention. It is noted that elastin is a polymer (i.e. a protein is a polymer of amino acids). '156 teach barrier layers (claim 1) and therapeutic agents (claim 6) as in the instant invention. It is noted that the elastin meet the structural limitations of the claims thus the functional limitations of claims 2-3 for example are necessarily met absence evidence to the contrary.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-3,12-16,18-19,22-23 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13,15-18 (2/15/08 claim set) of copending Application No. 10/497,442 ('442). Although the conflicting claims are not identical, they are not patentably distinct from each other.

'442 teach a wound dressing comprising a therapeutic agent and a barrier layer (claim 1). The barrier layer comprises proteins (claim 13) which are polymers of amino acids. '442 teach barrier layers (claim 1) and therapeutic agents (claim 1,2) as in the instant invention. It is noted that '442 meet the structural limitations (see claim 17 for example) of the claims thus the functional limitations of claims 2-3 for example are necessarily met absence evidence to the contrary. It is noted that although unclear (see 112 2nd) the configurations and layers of the

instant claims have been given the broadest reasonable interpretation (see MPEP section 2111) such that '442 (for example see claims 5-12) meet the claim limitations.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-3,6,11,13-16,18-19,22-23 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-17 (5/19/06 claim set) of copending Application No. 10/579,897. Although the conflicting claims are not identical, they are not patentably distinct from each other.

'897 teach a wound dressing comprising a therapeutic agent and a polymer and a linker group (claim 1). The linker group is specifically taught to be an oligopeptide sequence (claims 7-13 for example). '897 teach a configuration such that there is a matrix as in the instant claims. '897 teach thrombin as the inhibitor and the oligopeptide sequence of Gly-Arg-Gly-Asp (claim 12) as in instant claim 11. It is noted that '897 meet the structural limitations (see claim 17 for example) of the claims thus the functional limitations of claims 2-3 for example are necessarily met absence evidence to the contrary. It is noted that although unclear (see 112 2nd) the configurations and layers of the instant claims have been given the broadest reasonable interpretation (see MPEP section 2111) such that '897 (for example see claims 2-3) meet the claim limitations.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The claims as discussed above are directed to an invention not patentably distinct from the claims listed above of commonly assigned 10/529,156; 10/497,442; and 10/579,897. Specifically, see above.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned 10/529,156; 10/497,442; and 10/579,897, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

The examiner has identified four copending Applications/Patents which have been rejected under Double Patenting above. Because of Applicant's prolific Patent and Application portfolio, the burden is shifted to Applicant to identify all relevant Applications and Patents and to include said Applications and Patents on any terminal disclaimer filed.

Response to Arguments Double Patenting

Applicants argue that the rejection is moot because the subject matter of the co-pending applicants has not issued into a patent.

Applicant's arguments filed 3/11/08 have been fully considered but they are not persuasive.

The applicant has not overcome the outstanding rejections.

Conclusion

Applicants amendments necessitated a new search.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Woerly et al. (Biomaterials (2001 v22 pages 1095-1111). Woerly teach PHMPA interconnected with specific peptides such as GGRGD (abstract, Figure 1). Any rejection using Woerly would be repetitive of the rejections above.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RONALD T. NIEBAUER whose telephone number is (571)270-3059. The examiner can normally be reached on Monday-Thursday, 7:30am-5:00pm, alt. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ronald T Niebauer/
Examiner, Art Unit 1654

/Anish Gupta/
Primary Examiner, Art Unit 1654